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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/555,669	12/05/2008	Tzyy-Choou Wu	JHV-050.01	9879

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EXAMINER

BLUMEL, BENJAMIN P

ART UNIT	PAPER NUMBER
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1648

NOTIFICATION DATE	DELIVERY MODE
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04/29/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patent@foleyhoag.com

Office Action Summary	Application No. 10/555,669	Applicant(s) WU ET AL.	
	Examiner BENJAMIN P. BLUMEL	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/22/2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7-14,16-27,29-38 and 40-45 is/are pending in the application.
- 4a) Of the above claim(s) 11-14, 23-27, 29-38, 40-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7-10,16,20 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/7/05 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/7/05 and 3/11/2011</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I and the required species in the reply filed on 11/22/2010 is acknowledged.

However, upon further consideration, the species election of Group A) has been withdrawn.

Claims 11-14, 17, 19, 21, 23-27, 29-38, 40-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/22/2010.

Claims 1, 7-10, 16, 18, 20 and 22 are examined on the merits.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 11/7/05 and 3/11/2011 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 7-10, 16, 18, 20 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites, "...genome set forth in GENBANK Z95324 AL123456..."

However, it is unclear if applicants are referring to the GenBank accession #

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Z95324AL123456 or if this claim is referring to two different genomes. Moreover, if the claim is in fact referring to different accession numbers, each accession has more than one version in GenBank (see Appendices A and B). Therefore, it is unclear which version the claim is referring to. Claims 7-10, 16, 18, 20 and 22 are rejected since they depend from claim 1.

Claim 1 recites the limitation "(i)" in line 9. There is insufficient antecedent basis for this limitation in the claim.

Claims 20 and 22 recite, "...capable of inducing or enhancing an antigen-specific immune response..." However, it is unclear what level or type of immune response meets the limitations of "enhancing" since the claims do not require a comparison to another composition that can induce an immune response.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7-9, 16, 20, 22 rejected under 35 U.S.C. 102(b) as being anticipated by Wu and Hung (WO 01/29233).

The claimed invention is drawn to a nucleic acid molecule encoding a fusion polypeptide useful as a vaccine. The molecule comprises a nucleic acid sequence that

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encodes the peptide of SEQ ID NO: 10 (an HSP 70 protein of *M. tuberculosis*) or the carboxy terminus thereof, a sequence that encodes a signal peptide, and a nucleic acid sequence that encodes a viral antigen that which possesses an epitope that binds to a MHC class I protein. The viral antigen is that of a variant the E7 protein of human papilloma virus (HPV) serotype 16, which has the sequence of SEQ ID NO: 2. The claimed invention also requires an expression vector that contains the nucleic acid molecule with the above mentioned fusion protein operatively linked to a promoter and a pharmaceutical composition capable of inducing an antigen-specific immune response which comprises the nucleic acid molecule encoding a fusion protein or the expression vector and a pharmaceutically and immunologically acceptable excipient.

Wu and Hung teach the generation of a nucleic acid molecule that encodes a fusion protein and an expression vector, which contains a promoter and comprises the nucleic acid molecule. Either of these are formulated for in vivo applications by combining with a pharmaceutically acceptable excipient. An example of the nucleic acid encoding fusion protein taught by Wu and Hung includes a signal sequence; a full-length heat shock protein 70 or the carboxy terminus thereof, such as that of SEQ ID NO: 9; and a HPV E7 protein from HPV-16. The HSP 70 of SEQ ID NO: 9 is identical to SEQ ID NO: 10 of the instant invention and while Wu and Hung do not teach the sequence of their HPV-16 E7 protein, since it is from the same serotype as claim 8 requires, it at least meets the requirement of a variant of such a protein as recited in claim 9. Therefore, Wu and Hung anticipate the instant invention. See pages 2, 3, 7, 14, 26 and 34.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wu and Hung as applied to claims 1, 7-9, 16, 20 and 22 above, and further in view of Konishi et al. (Virology, 2000).

The claimed invention also requires that the expression vector comprises the plasmid PNGVL4a.

The teachings of Wu and Hung are discussed above, however, they do not teach the use of the plasmid PNGVL4a as their expression vector.

Konishi et al. teach the use of pNGVL4a in designing an expression vector for in vivo use since it lacks certain nucleic acid sequences that raise concerns when utilized as a DNA vaccine. See abstract.

It would have been obvious to one of ordinary skill in the art to modify the composition taught by Wu and Hung in order to utilize the expression vector pNGVL4a as their expression vector for in vivo applications. One would have been motivated to do so, given the suggestion by Wu and Hung that the composition generated for DNA immunization is based on an expression construct in a plasmid. There would have been a reasonable expectation of success, given the knowledge that the plasmid pNGVL4a is suitable for DNA immunization protocols, as taught by Konishi et al. Thus the invention

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as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wu and Hung as applied to claims 1, 7-9, 16, 20 and 22 above, and further in view of Edmonds and Vousden (Journal of Virology, 1989).

The claimed invention also requires that the E7 protein possesses a Glycine or Alanine in place of a Cysteine at position 24 as compared to SEQ ID NO: 2.

The teachings of Wu and Hung are discussed above, however, they do not teach an amino acid change to the E7 protein.

Edmonds and Vousden teach the mutation of the E7 protein from HPV-16 by changing the 24 amino acid from a Cysteine to a Glycine. See page 2651.

It would have been obvious to one of ordinary skill in the art to modify the composition taught by Wu and Hung in order to utilize a mutated E7 protein with a Glycine at position 24 in the described fusion protein expression construct. One would have been motivated to do so, given the suggestion by Wu and Hung that the encoded fusion protein include the E7 protein from HPV16. There would have been a reasonable expectation of success, given the knowledge that the E7 protein from HPV16 can be mutated at position 24 from a cysteine to a glycine, as taught by Edmonds and Vousden. Thus the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

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Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BENJAMIN P BLUMEL/
Examiner
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